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Sequence Number: () -() 7

Rule ID(s):

Effective Date:

File Date: (

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205

Agency/Board/Commission:	Tennessee Department of Mental Health and Developmental Disabilities
	Office of Licensure
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Revision Type (check all that apply):

Amendment

X New

Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables. Please enter only ONE Rule Number/RuleTitle per row)

Chapter Number	Chapter Title
0940-05-47	Minimum Program Requirements for Alcohol and Drug Outpatient Detoxification Treatment Facilities
Rule Number	Rule Title
0940-05-4701	Definition
0940-05-4702	Application of Rules
0940-05-4703	Policies and Procedures
0940-05-4704	Personnel and Staffing Requirements
0940-05-4705	Service Recipient Assessment Requirements
0940-05-4706	Individual Program Plan Requirements
0940-05-4707	Service Recipient Record Requirements
0940-05-4708	Professional Services
0940-05-4709	Service Recipient Medication Administration Requirements

Chapter Number	Chapter Title
Rule Number	Rule Title

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(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

0940-05-47-.01 Definitions

- "Alcohol and Drug Outpatient Detoxification Treatment Facilities" means organized outpatient services for service recipients to systematically reduce or eliminate the amount of a toxic agent in the body until the signs and symptoms of withdrawal are resolved. Outpatient detoxification treatment services are provided in regularly scheduled sessions in an office setting, health care or addiction treatment facility. The American Society of Addiction Medicine Patient Placement Criteria (ASAM PPC) is used to determine the level of outpatient detoxification services that will best meet a service recipient's needs.
- "Level II-D services with extended on-site monitoring" means outpatient services with daily assessment of progress during detoxification including serial nursing assessments using appropriate measures of withdrawal. This level of service is appropriate for service recipients at moderate risk of severe withdrawal syndrome who would safely respond to several hours of monitoring, medication and treatment.
- "Level II-D services without extended on-site monitoring" means outpatient services that may be provided daily or less frequently to service recipients with a minimal risk of severe withdrawal syndrome.

0940-05-47-.02 Application of Rules.

- (1) The governing body of alcohol and drug outpatient detoxification treatment facilities must provide services and facilities which comply with the following rules:
 - (a) Chapter 0940-05-04-.04(2) Life Safety Business Occupancies Rule;
 - (b) Chapter 0940-05-05 Adequacy of Facility Environment and Ancillary Services;
 - (c) Chapter 0940-05-06 Minimum Program Requirements for All Facilities;
 - (d) Chapter 0940-05-47 Minimum Program Requirements for Alcohol and Drug Outpatient Detoxification Treatment Facilities; and
 - (e) Chapter 0940-05-04-.09 Mobile Non-Ambulatory Rule if services are to be provided to one (1) or more mobile non-ambulatory service recipient.

0940-05-47-.03 Policies and Procedures.

- (1) The facility must maintain a written policy and procedure manual which includes the following:
 - (a) A description of the intake, assessment, and treatment process;
 - (b) A description of the aftercare service;
 - (c) Requirements that each employee or volunteer comply with procedures for detection, prevention, and reporting of communicable diseases according to procedures of the Tennessee Department of Health;
 - (d) Policies and procedures to ensure employees and volunteers practice standard precautions for infection control, as defined by the Centers for Disease Control (CDC);
 - (e) A quality assurance procedure which assesses the quality of care at the facility. This procedure must ensure appropriate treatment has been delivered according to acceptable clinical practice;
 - (f) Drug testing procedures if used by the facility;

- (g) Exclusion and inclusion criteria for service recipients seeking the facility's services;
- (h) Program admission criteria related to the results of the physical assessment;
- (i) Written admission protocols to screen for potentially aggressive or violent service recipients;
- (j) Policies and procedures which address the methods for managing disruptive behavior including techniques to deescalate anger and aggression;
- (k) If restrictive procedures are used to manage disruptive behaviors, policies and procedures that govern their use and minimally ensure the following:
 - 1. Any restrictive procedure must be used by the facility only after all less-restrictive alternatives for dealing with the problem behavior have been systematically tried or considered and have been determined to be inappropriate or ineffective;
 - 2. The service recipient must have given written consent to any restrictive measures taken with him/her by the staff;
 - 3. The restrictive procedure(s) must be documented in the individual program plan, be justifiable as part of the plan, and meet all requirements that govern the development and review of the plan;
 - 4. Only qualified personnel may use restrictive procedures and must be adequately trained in their use; and
 - 5. The adaptive or desirable behavior must be taught to the service recipient in conjunction with the implementation of the restrictive procedures.
- (I) If physical holding is used, a policy that requires it to be implemented in such a way as to minimize any physical harm to the service recipient and may only be used when the service recipient poses an immediate threat under the following conditions:
 - 1. The service recipient poses an immediate danger to self or others; and/or
 - 2. To prevent the service recipient from causing significant property damage.
- (m) Procedures for a physical examination by a physician, physician assistant or nurse practitioner as part of the initial assessment to determine the safety of providing detoxification services in an outpatient setting in accordance with Rule 0940-05-47-.05 Service Recipient Assessment Requirements.
- (n) Physician-approved protocols for service recipient observation, supervision, determination of appropriate level of care, and documentation of any concerns indicated by the protocol that need to be reviewed by a physician.
- (o) Procedures and criteria for more extensive medical intervention and/or transfer to a more intensive service, including an acute care hospital, if a service recipient has, at a minimum, any of the following conditions:
 - 1. A history of severe withdrawal, multiple withdrawals, delirium tremens, or seizures;
 - 2. Sustained extremes in heart rate;
 - Cardiac arrhythmia;
 - 4. Sustained extremes in blood pressure;

- 5. Unstable medical conditions including hypertension, diabetes or pregnancy.
- (p) Procedures to ensure that service recipients under age eighteen (18) will be treated separately from service recipients eighteen (18) years of age or older; and
- (q) Procedures to ensure that the facility, either directly or through arrangements with other public or private non-profit entities, will make available tuberculosis (TB) services in accordance with current Tennessee TB Guidelines for Alcohol and Drug Treatment Facilities (TB Guidelines), established by the Department of Health TB Elimination Program and the Department of Mental Health and Developmental Disabilities Division of Alcohol and Drug Abuse Services, including:
 - 1. Counseling the service recipients about TB;
 - Screening all service recipients for TB and, if applicable, testing service recipients at high risk for TB to determine whether the service recipients have been infected with TB; and
 - 3. Providing for or referring the service recipients infected by TB for appropriate medical evaluation, treatment, and case management activities.

0940-05-47-.04 Personnel and Staffing Requirements.

- (1) Direct services must be provided by qualified alcohol and drug abuse personnel.
- (2) All direct service staff in facilities providing alcohol and drug outpatient treatment detoxification services must receive documented training before having unsupervised direct contact with service recipients. Training topics must include implementing physician-approved protocols for the signs and symptoms of alcohol and other drug intoxification and withdrawal; monitoring withdrawal; assessing appropriate levels of care; supportive care; preparing service recipients for ongoing treatment; and facilitating entry into ongoing care.
- (3) Facilities must provide annual training to all direct service staff on supervising the selfadministration of medications.
- (4) The facility must employ or retain a physician with training or experience in addiction medicine by written agreement to serve as medical consultant to the program.
- (5) The facility must have a physician, physician assistant, or nurse practitioner available twenty-four (24) hours a day by telephone for medical evaluation and consultation.
- (6) The facility must have medical or nursing personnel to conduct a medical screening of service recipients to evaluate and confirm that detoxification in an outpatient setting is relatively safe for that service recipient.
- (7) Facilities providing Level II-D services with extended on-site monitoring must have medical or nursing personnel available for daily (seven days per week) monitoring, assessment, and management of symptoms of withdrawal and intoxification.
- (8) The facility must provide at least two (2) on-duty and on-site staff members certified in cardiopulmonary resuscitation (CPR), and trained in first aid, the abdominal thrust and standard precautions for infection control as defined by the Centers for Disease Control (CDC).
- (9) The facility must provide annual education about sexually transmitted diseases (STD), human immunodeficiency virus (HIV), and acquired immunodeficiency syndrome (AIDS) to all direct care staff
- (10) The facility must provide direct care staff with annual training in techniques to screen for potentially aggressive or violent service recipients and training in techniques to de-escalate anger

and aggression in service recipients.

(11) The facility must follow current TB Guidelines for screening and testing employees for TB infection.

0940-05-47-.05 Service Recipient Assessment Requirements.

- (1) The facility must document that the following assessments are completed at the time of admission; re-admission assessments must document the following information from the date of last service:
 - (a) Assessment of current functioning by trained staff according to presenting problem including addiction-focused history of the presenting problem;
 - (b) An assessment of any special needs such as co-occurring psychiatric and medical conditions, physical limitations, cognitive impairments, and support system issues;
 - (c) Basic medical history information and medical assessment to determine the necessity of a medical evaluation; and a copy, where applicable, of the results of the medical evaluation;
 - (d) A physical examination by a physician, physician assistant or nurse practitioner within twenty-four (24) hours of admission; and
 - (e) A history prior to admission of prescribed medications, frequently used over-the-counter medications, and alcohol or other drugs including patterns of specific usage for the past thirty (30) days prior to admission.

0940-05-47-.06 Individual Program Plan Requirements.

- (1) An Individual Program Plan (IPP) must be developed and documented for each service recipient within twenty-four (24) hours of admission and must include the following requirements:
 - (a) The service recipient's name;
 - (b) The date of development;
 - (c) Standardized diagnostic formulation(s) including, but not limited to, the current editions of the Diagnostic and Statistical Manual (DSM) and/or the International Statistical Classification of Diseases and Related Health Problems (ICD); and the American Society of Addiction Medicine Patient Placement Criteria for the Treatment of Substance-Related Disorders (ASAM PPC).
 - (d) Treatment priorities and goals with treatment objectives and activities designed to meet those objectives;
 - (e) Discharge plans for making referrals to address a service recipient's goals and needs;
 - (f) Assessment of progress through detoxification and any treatment changes; and
 - (g) Signatures of staff involved in treatment planning and documentation of service recipients' participation in the treatment planning process.

0940-05-47-.07 Service Recipient Record Requirements.

- (1) The individual's service recipient record must include the following:
 - (a) Documentation on a medications log sheet of all medications prescribed or administered including date, type, dosage, frequency, amount, and reason;

- (b) Documentation of a treatment protocol and schedule for detoxification and notes by qualified alcohol and drug or medical personnel that the protocol and schedule is being followed or exceptions to the protocol and schedule;
- (c) For facilities providing Level II-D extended on-site monitoring, documentation of daily (seven days per week) nursing assessments of withdrawal, progress during detoxification, and any treatment changes;
- (d) Reports of medical problems, accidents, seizures, illnesses and treatments for such accidents, seizures, and illnesses;
- (e) Reports of significant behavior incidents;
- (f) Reports of any instance of physical holding or restrictive procedures with documented justification and authorization; and
- (g) A discharge plan which states the date of discharge, status at discharge, reasons for discharge, and referral of the service recipient and their family or significant others to other services, as appropriate.

0940-05-47-.08 Professional Services.

- (1) The facility must provide outpatient treatment services necessary to assess needs, help the service recipient understand addiction and support the completion of the detoxification process.
- (2) Service recipients must be given instruction about dosages, appropriate use, and self-administration of medications.
- (3) The facility must plan for discharge to address service recipient needs as indicated in the assessment/history in the areas vocational, educational skills and academic performance; financial issues; cognitive, socio-emotional, and psychological issues; social, family, and peer interactions; physical health; community living skills and housing information. Such services may be provided directly by the agency or indirectly by referral to other service providers. Referral agreements with frequently used providers must be documented. The provision of such services to individual service recipients must be documented in the service recipient record at the facility.
- (4) The facility must document either by written agreements or by program services access to an interdisciplinary team of appropriately trained clinicians (such as physicians, registered nurses, licensed practical nurses, counselors, social workers and psychologists) to assess, obtain, and interpret information regarding service recipient needs. The number and disciplines of team members must be appropriate to the range and severity of the service recipient's problem.
- (5) The facility must document, either by written agreements or by program services, the provision of twenty-four (24) hour a day, seven (7) day a week availability of immediate medical evaluation and care.

0940-05-47-.09 Service Recipient Medication Administration Requirements.

- (1) When supervising the self-administration of medication, the facility must consider the service recipient's self-management skills and ability.
- (2) The facility must ensure that prescription medications are taken only by service recipients for whom they are prescribed and in accordance with the directions of a qualified prescriber.
- (3) Discontinued and outdated medication and containers with worn, illegible, or missing labels must be disposed.
- (4) All medication errors, drug reactions, or suspected inappropriate medication, use must be reported to the Medical Director of the facility who will report to the prescriber, if known.

- (5) Evidence of the current prescription of each medication taken by a service recipient must be maintained by the facility.
- (6) All direct service staff must be trained about medications used by the service recipient. This training must include information about the purpose and function of the medications, their major side effects and contraindications, and ways to recognize signs that medication is not being taken as prescribed or is ineffective for its prescribed purpose.
- (7) Staff must have access to medications at all times.
- (8) Schedule II drugs must be stored in a locked container within a locked compartment at all times and be accessible only to staff in charge of administering medication.
- (9) Staff must document each time a service recipient self-administers medication or refuses a medication. This documentation must include the date, time, medication name, and dosage, as well as over-the-counter medication. This documentation must be made on the medication log sheet in the service recipient's record.
- (10) For any service recipient incapable of self-administration, all medications must be administered by personnel licensed to administer medication.
- (11) All medications and other medical preparations intended for internal or external use must be stored in sanitary and secure medicine cabinets or drug rooms. Such cabinet or drug rooms must be kept securely kicked when not in use and the key must be in the possession of the supervising nurse or other authorized staff. Locks in doors to medicine cabinets and drug rooms must be such that they require an action on the part of staff to lock and unlock.

Authority: T.C.A. §§ 4-4-103; 4-5-202; 4-5-204; 33-1-302, 33-1-305, 33-1-309; and 33-2-301; 33-2-302; 33-2-403; and Executive Order Number 44 (February 23, 2007).

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
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Notice published in	the Tennesse	e Administrative Regis	ter on:	/15/2008	
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Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which shall be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

Memorandum

To:

Department of State

From:

Karen Edwards, Rules Coordinator

Subject:

Public Hearing Comments on Chapter 0940-05-47 Minimum Program Requirements for Alcohol

and Drug Outpatient Detoxification Treatment Facilities

Date:

November 26, 2008

The rulemaking hearing on Chapter 0940-05-47 Minimum Program Requirements for Alcohol and Drug Outpatient Detoxification Treatment Facilities was held at 1:30 p.m. on Wednesday, November 19, 2008 in the third floor conference room of the Cordell Hull Building in Nashville, TN. Other than staff of the Tennessee Department of Mental Health and Developmental Disabilities, only one member of the public, Stephanie Gibbs of Americhoice (Brentwood, TN), attended the public hearing. She offered no comments or suggestions. Furthermore, no comments were received by email, letter or fax prior to the close of business on November 19, 2008.

Regulatory Flexibility Addendum

Pursuant to Public Chapter 464 of the 105th General Assembly, prior to initiating the rule making process as described in § 4-5-202(a)(3) and § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

Chapter 0940-05-47 Minimum Program Requirements for Alcohol and Drug Outpatient Treatment Facilities only affects small businesses to the extent that a small business provides outpatient detoxification treatment services.

The proposed rule provides flexibility so that small businesses (and large businesses) may provide detoxification services in more cost effective outpatient settings, rather than in more expensive residential settings. Previously, only residential detoxification services were licensed. The proposed rules allow service recipients needing outpatient detoxification services to be monitored for some portion of the day but then go home when it is safe to do so. This reduces costs associated with providing twenty-four (24) hour residential treatment.

The two levels of outpatient detoxification treatment proposed allow providers to vary the types and numbers of staff and treatment intensity to match the needs of service recipients. Only service recipients meeting the criteria for Level II-D with extended on-site monitoring require periodic assessments by nursing personnel. If service recipients meet the criteria for Level II-D Services without extended on-site monitoring, they will be monitored daily or less frequently by qualified alcohol and drug personnel. These rules allow service providers to meet service recipient needs in a cost-effective manner.

All facilities providing outpatient detoxification services must comply with these rules. No exemptions from the rules will be allowed.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule:
- The Tennessee Department of Mental Health and Developmental Disabilities created two rules chapters to regulate outpatient and residential detoxification treatment services. This Chapter (0940-05-47) addresses only the regulation of outpatient detoxification services while Chapter 0940-05-44 regulates residential detoxification services. Previous rules promulgated by the Tennessee Department of Health combined regulations for alcohol and drug outpatient and residential detoxification services in the same set of rules.
- Rule 0940-05-47-.01 Definitions. This rule defines outpatient alcohol and drug detoxification treatment services. The rules allow for two levels of outpatient detoxification: with and without extended on-site monitoring. Department of Health rules did not make this distinction.
- Rule 0940-05-47-.02 Application of Rules. This rule provides licensees with all of the rules chapters, including facility and life safety rules, applicable to outpatient detoxification treatment facilities. Department of Health rules combined minimum program requirements as well as facility and life safety rules into a single chapter.
- Rule 0940-05-47-.03 Policies and Procedures. This rule prescribes the specific policies and procedures that must be developed by outpatient detoxification treatment facilities. Policy requirements do not differ significantly from previous requirements.
- Rule 0940-05-47-.04 Personnel and Staffing Requirements. This rule defines the qualifications of staff that must be employed in outpatient detoxification treatment facilities. Greater access to nursing staff is required for facilities providing outpatient treatment with extended on-site monitoring than for facilities without extended on-site monitoring.
- Rule 0940-05-47-.05 Service Recipient Assessment Requirements. This rule specifies the types of assessments required in outpatient detoxification treatment facilities. Because detoxification is provided in an outpatient setting, these rules require a physical examination within twenty-four (24) hours of admission. This is a new requirement.
- Rule 0940-05-47-.06 Individual Program Plan Requirements. This rule requires the development of an Individual Program Plan within twenty-four hours of admission. The required use of the American Society of Addiction Medicine Patient Placement Criteria, a nationally recognized assessment tool, for outpatient detoxification treatment is a new requirement.
- Rule 0940-05-47-.07 Service Recipient Record Requirements. This rule specifies the documentation that must be contained in the record of the service recipient. The requirement for daily nursing assessments for service recipients in outpatient detoxification treatment with extended on-site monitoring is a new requirement.
- Rule 0940-05-47-.08 Professional Services. This rule specifies services that must be provided at an outpatient detoxification treatment facility as well as those services that may be provided through agreements with other service providers. The requirement for access to an interdisciplinary team is a new requirement.
- Rule 0940-05-47-.09 Service Recipient Medication Administration Requirements. This rule specifies the policies and procedures needed to ensure that medications are stored and administered safely.
- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;
- T.C.A. § 4-4-103 Empowers the commissioner of each department to prescribe regulations
- T.C.A. § 4-5-202 Prescribes requirements for rulemaking hearings
- T.C.A. § 4-5-204 Describes how hearings will be conducted
- T.C.A. § 33-1-302 Empowers the department to make and enforce rules
- T.C.A. § 33-1-305 Empowers the commissioner to adopt rules necessary to enforce the department's responsibilities
- T.C.A. § 33-1-309 Requires conformity with the Uniform Administrative Procedures Act
- T.C.A. § 33-2-404 Requires the adoption of licensure rules
- T.C.A. § 33-2-301 Requires the department to set basic quality standards and supports for service recipients with mental health and developmental disabilities
- T.C.A. § 33-2-302 Requires the department to regulate compliance with quality standards
- T.C.A. § 33-2-403 Empowers the department to license services and facilities for service recipients for mental

health services

Executive Order Number 44 (February 23, 2007) Transfers the Bureau of Alcohol and Drug Abuse Services from the Department of Health to the Department of Mental Health and Developmental Disabilities

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Facilities providing outpatient detoxification treatment services will be affected by these rules. Prior to the adoption of the rules, the Department of Mental Health and Developmental Disabilities met with a committee of providers representing the Tennessee Association of Alcohol, Drug and Other Addiction Services, the Tennessee Association of Addiction and Behavioral Health Services, the Council of Alcohol and Drug Services, and the Tennessee Association of Mental Health Centers. Each of the organizations circulated the rules to their memberships. Changes recommended by these organizations were incorporated into the rules prior to the public hearing. The Notice of Public Hearing was sent to all alcohol and drug facilities. No organization or individual objected to the rules either before or at the Public Hearing.

(D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

None.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

None.

(F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Cynthia C. Tyler, Director, Office of Legal Counsel; Amber Gallina, Director, Office of Licensure; Karen Edwards, Rules Coordinator

(G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Cynthia C. Tyler, Director, Office of Legal Counsel

(H) Office address and telephone number of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

425 Fifth Avenue North, Office of Legal Counsel, Third Floor, Cordell Hull Building, Nashville, TN 37243; 615-532-6520.

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.